DEFENDANTS' BRIEF IN SUPPORT OF JOINT MOTION TO EXCLUDE PLAINTIFFS' EXPOSURE EXPERTS

24-MD-3101-JSC

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I. INTRODUCTION

To proceed past the general causation phase, Plaintiffs must provide reliable expert testimony that exposure to lead and/or arsenic at a level (or "dose") to which U.S. children could *realistically* be exposed from consuming Defendants' baby food products is capable of causing autism or ADHD. Because there is no scientific literature showing that dietary exposure to lead and arsenic at *any* dose can cause autism or ADHD in the real world, Plaintiffs have attempted to fashion an approach to expert testimony that has no precedent in law, science, or common sense.

As the first step, Plaintiffs engaged a dietician and an exposure scientist—Priscilla Barr and Rachael Jones, Ph.D.—to work in tandem to generate hypothetical lead and arsenic intake levels for hypothetical children who consume Defendants' baby food products. That process began with a set of seven hypothetical "menus"—one for each manufacturer Defendant—that each consist of a small subset of the myriad baby food products at issue in this MDL. Remarkably, neither Ms. Barr (the dietician) nor Dr. Jones (the exposure scientist) actually developed those menus. Instead, they were created entirely by Plaintiffs' counsel, who then asked Ms. Barr to review them and evaluate whether they were "plausible." As Ms. Barr understood it, she could deem the hypothetical menus "plausible" so long as it was theoretically *possible* for "any child" to consume them. Dr. Jones then took the attorney-dictated menus and calculated daily intake levels of lead and arsenic and estimated blood lead levels for a hypothetical child who consumed these foods with the frequency, in the amounts, and at the times Plaintiffs' counsel (not Dr. Jones) specified. As the second step, Plaintiffs' causation experts purported to rely on Dr. Jones' calculations to opine that exposure to this hypothetical "dose" of lead and arsenic could cause autism or (for lead only) ADHD.

Two overarching Rule 702 problems infect Ms. Barr's and Dr. Jones' opinions. *First*, they based their opinions on a demonstrably unreliable and unscientific method: rather than relying on their own background, training, and experience, both experts blindly accepted and relied upon assumptions, inputs, and even methods that Plaintiffs' counsel instructed them to use in their analyses. In creating the hypothetical menus, Plaintiffs' counsel cherry-picked a small fraction (25%) of the baby food products at issue in the MDL. Neither Ms. Barr, Dr. Jones, nor any other

Plaintiffs' expert can provide *any* explanation as to why those products were selected and others were ignored. Plaintiffs' counsel then directed Ms. Barr and Dr. Jones—who are supposed to be the experts on nutrition and exposure patterns—to *assume* the specific quantities, age ranges, and calendar years in which that consumption would occur. Both experts readily admit that they did not question why Plaintiffs' counsel chose these parameters, did not test these foundational assumptions against known science and data, and did not seek to verify the information they were provided or compare it to literature in their fields. In short, they did nothing but accept what they were told.

That is not a reliable scientific method. It is no method at all. Scientists in the real world do not rely on lawyers to design their experiments or choose the assumptions that go into their models, and they do not calculate exposures without asking any questions. In doing so here, Ms. Barr and Dr. Jones utterly failed to "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). In Dr. Jones' case, her decision to rely on inputs and assumptions from Plaintiffs' counsel without exercising any independent scientific thought led to initial exposure estimates with a 94% error rate—a core *Daubert* factor demonstrating unreliability.

Second, by the experts' own admission, Plaintiffs' counsel's hypothetical menus do not reflect a realistic level of exposure to lead and arsenic from consuming Defendants' baby food products. Simply put, those menus would never—and could never—be eaten by any child, anywhere. The menus assume, as Plaintiffs' counsel directed, that a child would eat the same combination of one Defendant's baby foods, in the same amounts, with the same levels of lead or arsenic, every day for months or years at a time. That is not just unrealistic—it is a factual impossibility. Because the exposure estimates based on the hypothetical menus bear no relation to realistic, human-relevant exposures from Defendants' baby foods, they are unreliable, do not "fit" the general-causation question, and are inadmissible under Rule 702.

II. FACTUAL BACKGROUND

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Plaintiffs' Counsel Created Hypothetical Menus of Limited Products Α. and Directed Their Experts to Assume, Without Investigation, **Consumption Periods and Patterns**

In a legitimate scientific setting, an expert conducting a chemical exposure assessment would use their own training and experience to identify all possible sources of exposure (e.g., food, air, or water, among others) and employ some accepted means of measuring the frequency and time periods of exposure (and other relevant parameters) based on reliable, real-world data sets and scientific knowledge. That is not what happened here. Instead, Plaintiffs' counsel—applying no disclosed methodology, scientific or otherwise—picked all the inputs and told their experts to use them.

Hypothetical Menus. To start, Plaintiffs' counsel prepared seven hypothetical menus of baby food products, one for each manufacturer defendant in the MDL. (Ex. 20, Barr Appendix D ["Hypothetical Menus"].¹) Plaintiffs have alleged that over 600 products manufactured by Defendants are "defective." (See Ex. 52, Appendix A to Master Complaint.) Yet Plaintiffs' counsel chose just 154 of those products—about 25% of the total—to include in their hypothetical menus. The menus do not specify why some products from Appendix A were included and others were not, and neither Ms. Barr nor Dr. Jones has any idea as to why or how those decisions were made.

That is because neither Ms. Barr nor Dr. Jones was involved in creating the hypothetical menus. (See, e.g., Ex. 39, Barr Vol. I Tr. 93:6-18 ["I did not create the menus."]; Ex. 41, Jones Vol. I Tr. 83:4-13 ["I did not participate in the development of the menus."].) Instead, Plaintiffs' counsel simply provided the menus to them and directed them to use those menus to formulate their opinions. (E.g., Ex. 39, Barr Vol. I Tr. 93:6-13; Ex. 41, Jones Vol. I Tr. 71:17-23.) Neither expert asked any questions about why Plaintiffs' counsel included some products but not others, or even what criteria were applied to decide which products should be included.

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Citations to "Ex. X" are to the exhibits attached to the Declaration of Livia M. Kiser, which is being filed simultaneously herewith.

Consumption Amounts and Timing. Next, Plaintiffs' counsel dictated the full range of consumption details that apply to a hypothetical child consuming the menus. These include:

- the age ranges during which particular products were consumed (i.e., 4 months to < 6 months; 6 months to < 1 year; 1 year to < 2 years; and 2 years to < 3 years);
- the quantities of each product consumed during each age range (e.g., 1 jar of Gerber Stage 2 Sweet Potatoes every day between ages 6 months to < 1 year);
- the total daily intake for each product category (e.g., jars, pouches) and overall—expressed in servings, grams, and kilocalories—during each age range (e.g., 370-400 kcals of Plum products every day between ages 2 years to < 3 years, and 790-850 kcals of Hain products every day between ages 2 years to < 3 years); and
- the time periods in which the products on the hypothetical menus were consumed (e.g., 2019 to 2021 for Beech-Nut and 2015-2017 for Gerber). These consumption periods were "defined so that [Dr. Jones] would know which years of [heavy-metal] testing data to use in [her] analysis." [Ex. 41, Jones Vol. I Tr. 88:8-11.]²

(See, e.g., Ex. 20, Hypothetical Menus at 1-5 [Beech-Nut Consumption Grid].) Although one would think that the expert witnesses would formulate these exposure factors based on their experience and expertise, Ms. Barr and Dr. Jones did not—Plaintiffs' counsel did that instead.

The hypothetical menus also included two explicit (and unrealistic) assumptions: (i) the hypothetical child consuming each of the Defendant-specific menus did not consume any breastmilk; and (ii) the hypothetical child consumed *only* that particular Defendant's baby food and no other brand. (*See, e.g., id.* at 1.) Again, neither expert knew why these assumptions were made, and neither attempted to compare these lawyer-generated inputs with what is known and reported in the literature about the food consumption patterns of U.S. babies or toddlers or with what is alleged in the complaints filed in this MDL.

Overall Consumption. The last instruction from Plaintiffs' counsel was the most outlandish. They directed the experts to assume that the hypothetical child consumed the exact same baby food

² Plaintiffs' counsel acknowledged that certain of Defendants' baby food products on the hypothetical menus were not actually available for sale during the entire hypothetical consumption period. For example, Plaintiffs' counsel directed their experts to assume that the hypothetical Beech-Nut menu was consumed *only* between 2019 and 2021—but multiple products on that menu (such as Stage 3 Organics Sweet Potato and Barley jars and Stage 2 Carrot, Apple & Pineapple pouches) were on the market only for a portion of that period. (Ex. 20, Hypothetical Menus at 5.)

products on each menu, in the exact same quantities, with no waste in any serving, every day, for the entire time period specified for each product. For example, the menu for Sprout Foods between ages 6 months to < 1 year assumes that the hypothetical child consumed *exactly* 5 servings of Sprout pouches (out of a list of only 6 pouch flavor options) and no other commercial baby food every single day for 6 months. (*See id.* at 25-26.) The Nurture menu assumes the hypothetical child consumed exactly 3 servings of Blueberry & Purple Carrot Yogis (a freeze-dried yogurt-based snack product) every day for two years (*id.* at 14)—meaning, in real numbers, that the hypothetical child consumed 66 Yogis per day for a total of approximately *550 bags* of Yogis over the course of two years. This, of course, could never happen in the real world, as Dr. Jones acknowledged. (Ex. 41, Jones Vol. I Tr. 158:13-159:7.)

B. Ms. Barr's Opinions

Ms. Barr is a registered dietician. She completed a one-year master's degree in nutrition in 2004 and has spent most of her career working at hospitals, primarily treating infants in the neonatal intensive care unit. (Ex. 19, Barr Appendix A.) Her work involves "determin[ing] the best nutrition plan for each patient," including advising on topics like "specialized diets for those with certain medical conditions, and alternate nutrition via tube or intravenously for those who are unable to eat" (Ex. 18, Barr Report at 1)—not developing commercial baby food diets for infants or toddlers to consume outside of a hospital over multiple years.

Ms. Barr was tasked with reviewing Plaintiffs' counsel's hypothetical menus and opining on whether they represented a "plausible pattern of consumption of each of the Defendants' baby food products." (*Id.* at 25; *see also id.* at 2.) Her plausibility assessment was based on only three factors: (1) caloric consumption; (2) age appropriateness of each product for the chosen age range; and (3) presence of certain key nutrients. (Ex. 40, Barr Vol. II Tr. 502:13-504:5.) Ms. Barr "did not take in heavy metal content into [her] evaluation at all." (*Id.* at 499:14-22.)

Ms. Barr did not select the products included on the hypothetical menus (*e.g.*, Ex. 40, Barr Vol. II Tr. 498:15-24); "did not come up with the consumption amounts" for any products (Ex. 39, Barr Vol. I Tr. 126:20-127:4); did not come up with "the specific age ranges" provided for in the hypothetical menus (*id.* at 130:2-9); and "do[es] not have any knowledge as to why [particular]

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years" of consumption (*e.g.*, 2019-2021) were selected for each Defendant or why those years were different for each defendant (*id.* at 159:24-160:20). Ms. Barr also was never told who created the hypothetical menus (Ex. 40, Barr Vol. II Tr. 497:11-21); "how [the menus] were created" (Ex. 39, Barr Vol. I Tr. 93:6-18); "why each hypothetical menu lists only one brand of product" (*id.* at 332:21-333:4); or "[why] any particular food [on the menus] was selected" (*id.* at 93:19-23). In Ms. Barr's words: "I wasn't made aware of why things were selected or who selected them." (Ex. 40, Barr Vol. II Tr. 498:15-21.)

Instead, Ms. Barr's role was limited to taking the hypothetical menus and—apparently without asking *any* questions about how those menus were prepared or why Plaintiffs' counsel chose the particular consumption patterns—evaluating the menus "for nutritional adequacy and plausibility." (Ex. 39, Barr Vol. I Tr. 93:6-13.) Although she purports to have experience in creating menus (*id.* at 123:16-24), Ms. Barr's only involvement in developing the final hypothetical menus here was to conduct a "preliminary review" of draft menus Plaintiffs' counsel sent her (*id.* at 109:21-111:10). Based on her review of those draft menus, Ms. Barr "reject[ed]" certain products and serving sizes on the draft menus that she deemed age-inappropriate. (*Id.* at 114:2-24.) But she did not provide Plaintiffs' counsel with any concrete suggestions for what products or serving sizes should be included on the menus instead. She would simply "give [her] feedback, and if they wanted to make changes, it's up to them." (*Id.* at 116:5-117:22.)

Ms. Barr then took the final hypothetical menus and reviewed them to see if they were "[p]lausible for consumption and nutritionally for key nutrients and such" based on her three factors. (Ex. 40, Barr Vol. II Tr. 501:21-502:2, 502:13-504:5.) As to caloric consumption, Ms. Barr's standard for "plausibility" was whether, *first*, the specified calories from baby food in the hypothetical menus met the *minimum* caloric needs for the 97th percentile of U.S. children in each age range (i.e., a child in the top 3% for height and weight), and, *second*, the number of calories did not *exceed* the average caloric intake for the 90th percentile of U.S. children in that age range (i.e., the top 10% heaviest eaters). (*Id.* at 503:19-504:5.) Ms. Barr acknowledged that she deliberately selected "an upper range of the level of normal of what somebody could potentially consume." (Ex. 39, Barr Vol. I Tr. 252:23-253:14.) But she nonetheless claims that the menus are somehow *also*

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(*Id.* at 261:18-262:10.)

Ms. Barr repeatedly emphasized that she is "not saying these menus are nutritionally optimal or average by any means." (Id. at 133:23-25; see also id. at 124:4-8, 141:13-15, 146:14-20.) Rather, her analysis focused strictly on whether the hypothetical consumption patterns were, in her view, "plausible." (Id. at 113:22-25 ["I was never evaluating for ... nutritionally optimal but more for just nutritional plausibility."].)

calorically plausible for children who are only in the 3rd or 50th percentile of height and weight.

Ms. Barr's definition of "plausible" is untethered to any scientific literature, health agency guidance, or accepted nutritional practice. She did not analyze whether the menus are "typical" or "average" consumption patterns for U.S. children. (*Id.* at 129:8-24, 145:25-146:9; Ex. 40, Barr Vol. II Tr. 495:3-7.) Nor did she attempt to determine whether the hypothetical menus "are actually representative of any specific child who has filed a lawsuit in this litigation." (Ex. 39, Barr Vol. I Tr. 333:12-19.) Ms. Barr did not, for example, compare the hypothetical menu products to the products on Appendix A to the Master Complaint or review any of the short-form complaints filed by MDL plaintiffs, which identify the Defendants' products they allegedly consumed. (Id. at 334:4-12; Ex. 40, Barr Vol. II Tr. 550:22-551:25.) To the contrary, she expressly disclaimed knowledge of "any specific child and their intake patterns from like these time periods." (Ex. 39, Barr Vol. I Tr. 333:12-19.)

Instead, Ms. Barr equated "plausibility" with "possibility." (Id. at 172:19-173:10 [Q. Is possible a synonym in your mind for plausible? A. **Yeah**. Could a child or more eat this consumption pattern. So is it possible. (emphasis added)]; see also id. at 277:3-9; Ex. 40, Barr Vol. II Tr. 502:6-12.) By Ms. Barr's standards, the hypothetical menus were "plausible" so long as "a child" or "any child" (i.e., one child) could possibly consume them—as opposed to whether the menus are representative of typical eating patterns. (Ex. 39, Barr Vol. I Tr. 123:25-124:8 ["[I]t was just about being nutritionally plausible. So that's – could a child consume this, like any child." (emphasis added)]; see also id. at 129:20-24, 145:25-147:3.)

In applying this unsupported definition of 'plausibility," Ms. Barr made no attempt to determine what methodology Plaintiffs' counsel may have used to develop the menus. (Id. at 97:4-

12.) Nor did she question Plaintiffs' counsel's reasons for selecting particular products from Appendix A over others. By her own admission, Ms. Barr was not "aware of *any scientific methodology or rationale* as to why certain product types were included or excluded from" the hypothetical menus. (*Id.* at 134:21-136:16 [emphasis added]; *see also* Ex. 40, Barr Vol. II Tr. 497:22-498:3.) As she put it, "I did not create the menu so that's not a question for me." (Ex. 39, Barr Vol. I Tr. 134:15-17.)

Applying her standard for "plausibility," Ms. Barr offers the opinion that each of the seven hypothetical menus created by Plaintiffs' counsel "present[s] a plausible pattern of consumption of each of the Defendants' baby food products." (Ex. 18, Barr Report at 25.)

C. Dr. Jones' Opinions

Dr. Jones is an exposure scientist and certified industrial hygienist who focuses primarily on assessing exposures in occupational settings. (Ex. 41, Jones Vol. I Tr. 29:19-30:1.) Most of Dr. Jones' work has focused on exposures to chemicals or pathogens via inhalation, with a lesser emphasis on exposures to airborne contaminants, drinking water, and noise. (*Id.* at 26:19-27:7, 30:21-31:7.) She has never published any research on exposure to lead from any source, or on exposure to arsenic in foods. (*Id.* at 28:4-18, 29:1-6.) By her own account, her "work has not been focused on food" at all. (*Id.* at 26:19-27:7.) Aside from providing general overviews of dietary exposure assessments in her teaching, Dr. Jones could not identify a single exposure assessment related to food consumption that she has conducted in her decades-long professional career. (*Id.* at 27:9-16.)

Dr. Jones was responsible for taking as a given the hypothetical menus and consumption patterns that Plaintiffs' counsel created, and using Defendants' heavy metal test results to estimate the daily levels of lead and arsenic a hypothetical child consuming those menus would be exposed to. Dr. Jones prepared three sets of exposure calculations:

- "mean" (average) and "maximum" daily intake levels of lead she claims would exist from consuming each Defendant-specific menu during each specified age range
- "mean" and "maximum" daily intake levels of arsenic she claims would exist from consuming each Defendant-specific menu during each specified age range

• "mean" and "maximum" estimated blood lead levels she claims would result from consuming each Defendant-specific menu during each specified age range.

(See, e.g., Ex. 24, Jones Amended Rebuttal Report at 33 [Table 29].)

Like Ms. Barr, Dr. Jones did not select any of the Defendants' products included in the hypothetical menus (Ex. 41, Jones Vol. I Tr. 70:12-17), and she "do[esn't] know the basis for the decisions about the consumption patterns" (*id.* at 106:16-23). Dr. Jones also does not know whether the hypothetical menus are "similar to the menu of products consumed by any child in this litigation" or "by any child in the United States." (*Id.* at 73:8-23, 74:1-8.) And Dr. Jones made no attempt to evaluate how those menus were developed; why Plaintiffs' counsel selected particular products, age ranges, consumption time windows, or consumption amounts for each Defendant; or whether any of the assumptions in those menus were "consistent with the consumption of these types of baby food products in the real world." (*Id.* at 82:7-83:20; 88:1-23; 103:7-104:10; 106:16-23.) Instead, Dr. Jones simply accepted the consumption patterns as they were and used them to calculate exposure levels without doing anything to verify or test them.

This meant that Dr. Jones—the exposure scientist—did not conduct *any* independent analysis of the hypothetical child's lead or arsenic exposure sources because Plaintiffs' counsel instructed her to assume all the key inputs for her calculations. (*Id.* at 65:2-68:21; *see also* Ex. 18, Hypothetical Menus.) All that was left for Dr. Jones to do was to review Defendants' heavy metal test results for the products and years selected by Plaintiffs' counsel and decide how to calculate estimated exposures to arsenic and lead.

There, too, Plaintiffs' counsel did most of the work. Throughout the course of the litigation, Defendants have produced heavy-metal test results for various products and ingredients, including Excel spreadsheets of test results and certificates of analyses from various testing labs. But although Dr. Jones was given copies of many of the test results produced by Defendants, she did not independently review any of those documents when preparing her opening report. Instead, *Plaintiffs' counsel* determined which test results Dr. Jones would use for her calculations and compiled those test results into Defendant-specific spreadsheets that they then gave to Dr. Jones. (Ex. 21, Jones Opening Report at 12; *see also* Ex. 41, Jones Vol. I Tr. 15:6-14.) That required some

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unknown person(s) from Plaintiffs' law firms to review the underlying Bates-stamped documents and—among other tasks Dr. Jones should have performed—decide which test results to include or exclude among the thousands produced, identify potential duplicate test results, and decide how to report the test results. Deciding how to report particular test results required the unknown spreadsheet-compiler to determine whether particular results were reported as "below a level of detection" (as opposed to reporting a specific lead or arsenic level); whether an ingredient lot corresponding to a particular result was rejected or destroyed (such that the ingredient lot was not used in any baby food product that was actually sold); and more.

Dr. Jones does not know who created those spreadsheets or reviewed the underlying records to populate the spreadsheets with particular heavy metal test results. (Ex. 41, Jones Vol. I Tr. 16:18-17:15.) Despite not knowing "anything" about the person(s) who prepared the spreadsheets (Ex. 42, Jones Vol. II Tr. 625:1-626:13), Dr. Jones assumed "[t]hat the data provided to [her] had been cleaned and verified for completeness and accuracy" before the spreadsheets were provided to her (Ex. 41, Jones Vol. I Tr. 44:4-45:11.) She therefore did not "do anything to check the accuracy of the heavy metal test results that were listed for certain products in the spreadsheets" against the Bates-stamped test results produced by Defendants. (Id. at 19:3-8.) Instead, she blindly relied on the information in those spreadsheets to run her exposure calculations.

Taking all of the inputs and methods dictated by Plaintiffs' counsel, Dr. Jones calculated a "mean" (i.e., "average") and "maximum" daily intake level (expressed in micrograms, or "parts per billion," per day) of arsenic and lead, respectively, for each Defendant and each age range in the hypothetical menus. (*Id.* at 116:18-25; see also Ex. 24, Jones Amended Rebuttal Report at 33.)

The final step in Dr. Jones' analysis was to attempt to estimate the hypothetical child's blood lead levels during specific age ranges by using the EPA's Integrated Exposure Uptake Biokinetic ("IEUBK") model. The IEUBK model "predicts blood lead levels (PbB) in young children (birth to 7 years of age) exposed to lead from several sources of exposure and routes." EPA, Estimation of Dietary Lead Exposure: Update to the Default Values for the Integrated Exposure Uptake Biokinetic Model for Lead in U.S. Children ["EPA Dietary Default Values for IEUBK Model"] at 1, https://semspub.epa.gov/work/HQ/400706.pdf. The IEUBK model is publicly available online;

anyone can download it, input numbers in the exposure fields the program uses to model lead levels in blood, and generate estimated population-level blood lead levels based on those inputs. (Ex. 41, Jones Vol. I Tr. 213:8-17.) Prior to this case, Dr. Jones had never used the IEUBK model and had never calculated estimated blood lead levels using *any* method. (*Id.* at 208:5-209:4.)

Based on the understanding that children—like all humans—are naturally exposed to lead from a variety of sources, the IEUBK model is designed to evaluate lead exposure from six different sources: soil and dust, air, drinking water, food, maternal blood, and alternate exposures. (*Id.* at 211:18-212:9.) The EPA has promulgated "default" exposure levels for each of those exposure sources based on real-world data on lead exposure in the U.S. (*Id.* at 220:16-23; *see also* EPA Dietary Default Values for IEUBK Model at 3.) So, for example, if specific information about a particular exposure source—such as air—is not available, the researcher can populate the "air" field of the model with the EPA's default value for lead exposure from air. Here, rather than using EPA's default levels for the sources specified in the model or attempting to calculate the hypothetical child's exposure to lead from any of those sources, Dr. Jones input only one exposure source into the "food" field of the model: "consumption of defendants' baby food products." (Ex. 41, Jones Vol. I Tr. 178:21-179:5.) She then manually entered a "0" for the five remaining exposure source fields. (*Id.* at 213:19-214:6.) As a result, her estimated blood lead levels reflect hypothetical exposures from consuming Plaintiffs' counsel's hypothetical menus *only*.

Dr. Jones' initial report included summary tables reflecting her estimated lead and arsenic daily intake levels and estimated blood lead levels for each Defendant-specific menu and consumption pattern during each age range. (See Ex. 22, Jones Opening Report Summary Tables.)

After Dr. Jones submitted her opening report, defense expert Dr. Carolyn Scrafford (an exposure scientist) submitted an expert report identifying numerous methodological and data-entry errors in Dr. Jones' analyses. Among many other errors, Dr. Scrafford pointed out that Dr. Jones had failed to exclude many duplicate test results; relied on test results for certain ingredient lots that had been rejected or destroyed; relied on certain test results from outside the "consumption periods" selected by Plaintiffs' counsel; and failed to treat test results designated as "below the level of

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detection [or quantification]" consistently. (See Ex. 41, Jones Vol. I Tr. 41:10-42:5, 43:9-18, 45:13-46:15, 274:23-276:15.)

After reviewing Dr. Scrafford's report, Dr. Jones attempted to fix the errors Dr. Scrafford identified and submitted a rebuttal report that included revised exposure calculations. (Id. at 39:9-41:8.) Dr. Jones' opening report included a total of 222 individual calculations across all seven Defendants. In her rebuttal report, 208 of those calculations (or nearly 94%) had changed—many by a large degree. (Ex. 23, Jones Rebuttal Report at 15, 22, 29, 34, 40, 46, 54.) For example, Dr. Jones' original estimated mean blood lead level from Hain menu products for ages 6 months to < 1 year dropped by nearly half, from her original estimate of 6.1 micrograms per deciliter (ug/dL) to her modified estimate of 3.2 ug/dL. (Id. at 29.) Dr. Jones had also originally estimated that a child consuming the Hain menu from ages 1 year to < 2 years would have a maximum daily arsenic intake level of 415 ug/day. In her rebuttal report, that estimate plummeted to 52.2 ug/day—an 84.7% drop. (*Id*.)

At her deposition, Dr. Jones explained that her exposure numbers had changed in her rebuttal report because, after reading Dr. Scrafford's report, she decided—for the first time—to "[go] back to look at duplications and some potential data entry errors" in the spreadsheets Plaintiffs' counsel had provided her. (Ex. 42, Jones Vol. II Tr. 628:23-629:6.) On reviewing the spreadsheets, Dr. Jones identified *thousands* of erroneously included test results. For Hain, for example, Dr. Jones removed a little over two thousand duplicate ingredient test results that she had incorrectly included in her initial calculations—more than 50 percent of the total test results she had originally used for Hain. (Id. at 645:9-647:7.) Having purportedly corrected those errors (and many others) in her original estimates, Dr. Jones testified that the estimates in her rebuttal report were complete and accurate. (Ex. 41, Jones Vol. I Tr. 58:24-59:9.)

Dr. Jones was then questioned at her deposition about a series of additional errors underlying her *revised* calculations, including (1) her continued inclusion of duplicate test results that skewed the exposure estimates for certain Defendants upwards (e.g., Ex. 42, Jones Vol. II Tr. 683:11-684:3); (2) her erroneous inclusion of test results for ingredient lots that were ultimately rejected (id. at 732:8-735:20); and (3) Plaintiffs' counsel's failure to include all relevant test results in the

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spreadsheets (*id.* at 697:6-698:21). Despite being confronted with multiple additional errors, Dr. Jones testified that nothing she learned during the deposition "ma[d]e [her] think that [her] results were scientifically unreliable or that [her] results were not sound." (*Id.* at 801:18-25.)

One month later, however, Dr. Jones submitted an "Amended Rebuttal Report" with a *third* version of her exposure estimates. (Ex. 24, Jones Amended Rebuttal Report.) This time, Dr. Jones addressed some—but not all—of the errors pointed out during her deposition and identified yet *more* errors in her calculations. Notwithstanding the fact that she had already been confronted with numerous errors she had missed in her first two iterations of calculations, Dr. Jones claimed that she does "not anticipate that these values" in her third round of estimates, "would meaningfully change in the future, even if additional testing results are identified as duplicates, subject to data entry errors, or excluded for other reasons." (*Id.* at 34.)

D. Plaintiffs' Causation Experts Wholly Depend on Dr. Jones and Ms. Barr

Plaintiffs' experts who offer causation opinions—Drs. Ritz, Gardener, Hu, Guilarte, and Aschner³—purportedly used Dr. Jones' estimates to support their opinions that exposure to lead and arsenic from Defendants' baby food products can cause autism and ADHD. These experts initially relied on Dr. Jones' original exposure estimates. But with each round of revised estimates (many of which declined sharply), each expert submitted a supplemental report simply stating that the revised calculations continued to support their causation opinions.

III. ARGUMENT

A. Ms. Barr's and Dr. Jones' Blind Reliance on Assumptions and Methods Directed by Plaintiffs' Counsel Renders Their Opinions Unreliable

Ms. Barr's and Dr. Jones' opinions are founded entirely on a towering series of unsupported—and unsupportable—assumptions, inputs, and methods dictated to them by Plaintiffs' counsel. Every single variable they relied on in conducting their analyses was selected by the

³ Although Dr. Kevin Shapiro is technically labeled a "causation" expert by Plaintiffs, he does not purport to rely on Dr. Jones' calculations (or indeed, any "specific exposure amounts") to support his opinions. (Ex. 36, Shapiro MDL Vol. I Tr. 14:13-21.) Instead, he merely offers an opinion on what he refers to as "the general plausibility of a *mechanistic link* between exposure to heavy metals and *symptoms* of autism and ADHD." (*Id.* at 14:22-15:4 [emphasis added].)

attorneys. At every turn, Ms. Barr and Dr. Jones blindly accepted these inputs—taking no steps to test those assumptions or even pausing to consider whether they are reliable based on real-world data sets or government agency guidance or whether they instead reflect cherry-picking by Plaintiffs' counsel to support a particular outcome.

Experts are permitted to rely on facts or reasonable assumptions provided to them by counsel. But nothing in Rule 702 (or any other Rule) permits an expert to abdicate all independent scientific judgment, unquestioningly rely on assumptions from non-scientists, or fail to test or verify the premises that form the entire foundation of their opinions. To the contrary, "experts are expected to verify the reliability of the data underlying their conclusions instead of simply adopting the representations of an interested party." *Baker v. Firstcom Music*, 2018 WL 2676636, at *2 (C.D. Cal. May 8, 2018); *see also Lyman v. St. Jude Med. S.C.*, 580 F. Supp. 2d 719, 726 (E.D. Wis. 2008) (excluding expert who accepted key data "at the word of [defense] counsel" without "independently verifying [its] reliability"). Unscientific reliance on attorney-provided inputs is not a sound methodology, and Dr. Jones' and Ms. Barr's failure to assess or test any of Plaintiffs' counsel's inputs renders their opinions unreliable in multiple ways.

1. Dr. Jones' and Ms. Barr's Opinions Do Not Reflect the Level of Intellectual Rigor of Experts in Their Fields

In a typical products liability case, one would have expected Ms. Barr and Dr. Jones to use their experience in infant nutrition and exposure science to attempt (in Ms. Barr's case) to create a plausible consumption pattern for the baby food products at issue in the MDL and (in Dr. Jones' case) to do her own data-gathering to estimate realistic levels of lead and arsenic exposure from consuming those products. But here, Plaintiffs' lawyers did all of that work instead. Plaintiffs' counsel decided which (small) subset of products to include for each Defendant, the quantities of each product to be consumed, the consumption age ranges for each product, and the relevant years for heavy-metal test results. They then invented additional scientifically unsound assumptions (such as "one baby food brand only") about the hypothetical child's diet. *See supra* at 3-5. For Dr. Jones, Plaintiffs' counsel took the extra step of compiling the particular heavy metal test results for her to rely on in generating her exposure calculations. (*See* Ex. 21, Jones Opening Report at 12; Ex. 41,

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Jones Vol. I Tr. 15:6-14.) Not only did Dr. Jones and Ms. Barr have no real role in these processesthey had no insight at all into how Plaintiffs' counsel had done any of it, who was responsible for doing this work, or what their qualifications may or may not be. See supra at 5, 9-10.

Despite knowing nothing about the foundations of Plaintiffs' counsel's assumptions, Ms. Barr and Dr. Jones accepted all of them without question. Ms. Barr did not even try to compare the products on the hypothetical menus to the list of products at issue in the MDL. Nor did she make any affirmative suggestions for specific products or quantities to include in the hypothetical menus. (Ex. 39, Barr Vol. I Tr. 109:21-111:10, 114:2-24, 116:5-117:22.) And Dr. Jones, who is trained in conducting exposure assessments, gave no consideration to what methods were used to prepare the consumption patterns or testing-data spreadsheets—notwithstanding the fact that those materials provided her with every input that went into her assessment. She simply "followed the specified consumption pattern" exactly as it was without asking any questions (Ex. 41, Jones Vol. I Tr. 159:25-160:11), and "assumed" without confirming that the testing-data spreadsheets were accurate and contained all the information she needed to run her calculations reliably (id. at 19:3-8, 44:4-45:11). When pressed at deposition as to whether they made *any* efforts to question or verify any of Plaintiffs' counsel's many assumptions or compare those assumptions against known science or accepted guidelines in their fields, Dr. Jones and Ms. Barr repeatedly stated that such inquiries were "outside the scope of their task." (E.g., Ex. 41, Jones Vol. I Tr. 85:6-16, 112:17-25, 244:21-245:3; Ex. 42, Jones Vol. II Tr. 510:2-11, 517:4-519:5; Ex. 39, Barr Vol. I Tr. 150:9-22, 154:18-155:6, 338:7-339:20.)

Under Rule 702, however, the opposite is true—as the proffered experts, that was their task. Blind reliance on foundational assumptions or inputs from non-scientists does not reflect the "level of intellectual rigor that characterizes the practice" of experts in nutrition or exposure science. Kumho Tire, 526 U.S. at 152. And here, Dr. Jones and Ms. Barr made clear that what they did in this litigation in no way resembles the processes and methods they employ outside the courtroom. When conducting scientific research, Dr. Jones typically "work[s] together as a team of investigators to decide the scope of the question and what information needs to be gathered" for an exposure assessment—she does not rely on others to tell her every exposure variable to consider without

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asking any questions. (Ex. 41, Jones Vol. I Tr. 115:14-116:14.) And while Dr. Jones has, on occasion, done work for a regulatory body like OSHA "where they tell [her] they want ... specific assumptions," the individuals providing the assumptions in that context are "scientists." (*Id.*) Here, Dr. Jones had no idea who came up with the assumptions on which her opinions are based, yet she accepted them without question. For her part, Ms. Barr could not recall any other instance when she has been given a hypothetical menu, told to accept all the inputs on that menu, and determine if that menu was nutritionally "plausible" without proposing any alternatives. (Ex. 40, Barr Vol. II Tr. 504:19-508:23.) As she put it, "[i]f it was in my practice I would try to make it nutritionally optimal" (id. at 508:12-23 [emphasis added]), yet she repeatedly made clear that she did not try to do so here—she did not even try to make menus that were "typical" or "likely" (id. at 495:3-7; see also Ex. 39, Barr Vol. I Tr. 129:8-24, 145:25-146:9). These kinds of departures from the standards and practices of experts in Dr. Jones' and Ms. Barr's fields are a hallmark of unreliable opinions that do not satisfy Rule 702.

Equally troubling, Dr. Jones' and Ms. Barr's blind reliance on inputs dictated by Plaintiffs' counsel leaves Defendants and the Court wholly unable to assess the methods (if any) underlying their opinions. Under Rule 702, "[e]xperts must follow some discernable methodology, and may not be 'a black box into which data is fed at one end and from which an answer emerges at the other." GPNE Corp. v. Apple, Inc., 2014 WL 1494247, at *4 (N.D. Cal. Apr. 16, 2014) (citation omitted). Dr. Jones and Ms. Barr *admit* that the assumptions and inputs on which their opinions are based are a "black box" even to them. The numerous untestable, unexplained, lawyer-driven assumptions about product selection, quantities, time periods, and age ranges underlying the hypothetical menus cannot pass muster under Rule 702.

2. Dr. Jones Did Not Consider Whether Plaintiffs' Counsel's **Assumptions Reflected Unreliable Cherry-Picking**

One consequence of Dr. Jones' decision to blindly accept Plaintiffs' counsel's inputs is that she did not evaluate or even consider how the levels of lead or arsenic for the products and years included in the hypothetical menus compared to the levels for Defendants' products and years that

Plaintiffs' counsel *omitted* from the menus. In other words, Dr. Jones made no effort to determine whether the hypothetical consumption patterns were cherry-picked to achieve a certain result.

Dr. Jones could have done that analysis. The spreadsheets Plaintiffs' counsel provided to her included lead and arsenic test results for products other than those in the hypothetical menus. Despite having access to these additional test results, Dr. Jones made no effort to compare them with the lead and arsenic results for the products on the lawyer-selected menus or do any kind of analysis to see how Plaintiffs' counsel's product choices affected her estimates. (Ex. 41, Jones Vol. I Tr. 77:14-78:4.) Unsurprisingly, when defense expert Dr. Robert Gibbons conducted a statistical analysis of the hypothetical menus, he confirmed that Plaintiffs' counsel cherry-picked products made with vegetables and grains (*e.g.*, sweet potatoes, rice cereal) that generally have higher lead or arsenic levels than others—and that those selections had a statistically significant impact on many of Dr. Jones' resulting estimates. (*See* Ex. 25, Gibbons Report at 21-23.)

Likewise, despite having test results for years outside of the lawyer-selected consumption periods, Dr. Jones did not even try to evaluate whether the heavy metal levels for any product on the menus were lower in other years than the levels for the *same* product during the years Plaintiffs' counsel directed her to include. (Ex. 41, Jones Vol. I Tr. 90:24-91:19, 93:5-15.) Dr. Jones also gave no thought to why Plaintiffs' counsel selected *different* consumption years for each Defendant—*e.g.*, 2015-2017 for Gerber and 2019-2021 for Beech-Nut—or whether that decision was motivated by particular heavy-metal test results from those years. (*Id.* at 88:1-23.) For example, Plaintiffs' counsel dictated a consumption period of 2017-2019 for Hain, even though numerous plaintiffs allegedly consumed Hain's products between 2020-2025. (*See* Ex. 20, Hypothetical Menus at 11, 13 [Hain Consumption Grid].) Choosing that *earlier* time period, coincidentally, meant that Dr. Jones' calculations excluded all Hain testing data from 2020 onward, when Hain began conducting "finished product" testing (which has uniformly lower levels of lead and arsenic than its earlier ingredient testing, where Hain often simply recorded results as "below" a particular specification level).

Similarly, Plaintiffs' counsel's choice of 2017-2019 as the consumption period for Plum meant that a single outlier test result from 2017—which showed a lead level *32 times* higher than

the next closest result for the same Plum product—was included in Dr. Jones' mean daily lead intake estimates for that age range. (Ex. 41, Jones Vol. I Tr. 143:20-145:13.) Of course, that single outlier result skewed Dr. Jones' daily intake estimates for Plum dramatically upward. If Plaintiffs' counsel had picked a different consumption period—such as 2019-2021, as for Beech-Nut and Sprout—that test result would have been excluded. (See Ex. 20, Hypothetical Menus at 2, 26.) Yet Dr. Jones did not question that decision at all. Her failure to ask any questions about the consumption periods is particularly striking given that the hypothetical menus explicitly state that many products on those menus (which Plaintiffs' counsel chose) were not even on the market throughout the consumption periods (which Plaintiffs' counsel also chose). (Id. at 5, 9, 13, 18, 24, 28, 33.)

Dr. Jones also did not compare the list of 154 products included on the hypothetical menus with the list of 600+ products in Appendix A to the Master Complaint, to see whether Plaintiffs' counsel's selection process reflected cherry-picking designed to reach a certain result. (See Ex. 41, Jones Vol. I Tr. 79:14-80:12.) For example, Appendix A includes 21 non-rice-based infant cereals, but zero non-rice cereals are included on the hypothetical menus. Meanwhile, Appendix A includes 6 rice cereals (which are known to contain higher levels of arsenic than non-rice cereals on average), and 4 of those 6 rice cereals are included in the hypothetical menus. (Compare Ex. 52, Appendix A to Master Complaint to Ex. 20, Hypothetical Menus.) Although Dr. Jones knows that rice cereals generally have higher levels of arsenic than non-rice cereals (Ex. 41, Jones Vol. I Tr. at 86:21-87:8), she gave no thought to why the hypothetical menus feature 4 of the 6 rice cereals in Appendix A but none of the 21 non-rice cereals—even after defense expert Dr. Scrafford pointed out that disparity in her report (id. at 83:22-85:4). According to Dr. Jones, thinking about that was, as with every other substantive decision, "outside the scope of my task." (Id. at 85:6-86:12.)

Courts in this District routinely exclude under Rule 702 expert opinions based on cherry-picked data that attempt to favor one party's position. *See, e.g., In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176, 1184 (N.D. Cal. 2007); *Waymo LLC v. Uber Technologies, Inc.*, 2017 WL 5148390, at *3-4, *8 (N.D. Cal. Nov. 6, 2017); *Rearden LLC v. Walt Disney Co.*, 2021 WL 6882227, at *7 (N.D. Cal. July 12, 2021). Because Dr. Jones simply accepted Plaintiffs' counsel's decisions without question, she has no way of knowing whether the

hypothetical menus are the result of an inadmissible cherry-picking process engineered by those attorneys, or whether her exposure calculations are a reliable estimation of real-world exposures to Defendants' products. That failure of analysis, too, renders her opinions unreliable.

3. Dr. Jones Failed to Assess Whether Her Exposure Estimates Were Realistic in Light of Real-World Data on Blood Lead Levels

Dr. Jones similarly failed to perform any analysis of whether the estimated blood lead levels (or "BLLs") generated by Plaintiffs' counsel's inputs were reliable—or made any sense at all—in the context of known, real-world scientific data on lead exposures in U.S. children.

Dr. Jones acknowledged CDC data showing that 97.5% of U.S. children ages 1-5 have a BLL below 3.5 ug/dL. (Ex. 21, Jones Opening Report at 18; *see also* Ex. 41, Jones Vol. I Tr. 245:5-15.) The CDC has also published data showing that the average BLL of U.S. children ages 1-5 is 0.83 ug/dL. *See* Egan et al., *Blood Lead Levels in U.S. Children Ages 1-11 Years*, *1976-2016* at 1 (2021), https://ehp.niehs.nih.gov/doi/epdf/10.1289/EHP7932. Of course, those real-world BLLs reflect children's exposures to lead from *all* sources (including air, water, dust, soil, table foods, and more)—not just commercial baby foods. (*See* Ex. 41, Jones Vol. I Tr. 246:3-247:2.)

Dr. Jones' estimated BLLs purport to reflect lead exposure from Defendants' baby food products *only*. *See supra* at 11. Yet her original exposure calculations for Hain generated an estimated mean BLL of *6.1 ug/dL* for children aged 6 months to < 1 year. (Ex. 22, Jones Opening Report Summary Tables.) In other words, Plaintiffs' counsel's inputs for Hain resulted in estimated BLLs *from baby food products alone* that were nearly two times higher than the *actual* BLLs of the 97.5th percentile of U.S. children *from all sources of lead*—and nearly *eight times higher* than the national average. That result defies logic and common sense. And it would have been a signal to any exposure scientist outside of litigation that something may be amiss with the inputs she received.

Dr. Jones' estimated BLLs also run counter to real-world data on the extent to which lead is actually *absorbed* when infants consume commercially prepared foods, milk, and formula. The only peer-reviewed study that has modeled absorption of lead through a complex mixture like food or milk at a relevant dose showed that when lead intake is less than 5 ppb per kilogram of body weight daily, lead excretion *exceeded* absorption. (*See* Ex. 85, Ziegler (1978).) In other words, the

children did not actually retain the lead they ingested in those foods. Dr. Jones admitted that she did not factor this real-world data on dietary lead absorption rates into her analyses, yet she stood staunchly by her estimates. (Ex. 42, Jones Vol. II Tr. 535:20-537:20.)

When an exposure scientist obtains a result contrary to verified data and peer-reviewed literature, a reliable method would be to adjust her assumptions or do something to determine why the assessment yielded results that are obviously contrary to existing knowledge. Instead, Dr. Jones simply "assumed [her BLL estimates were] correct because of the data that had been provided to [her] by Plaintiffs" and because of her "methodology"—which was to accept the data without further analysis. (Ex. 42, Jones Vol. II Tr. 615:13-616:7, 616:17-19.) It was not until errors in her calculations were pointed out to her by defense experts and counsel that Dr. Jones revised her BLL calculations, *twice*, to reach her current estimates. *See supra* at 11-13. That kind of unthinking reliance on attorney-provided assumptions in the face of real-world data casting doubt on those assumptions highlights why her methodology was unreliable.

4. Dr. Jones' Exposure Calculations Were Riddled with Additional Errors that Rendered Her Estimates Unreliable

Dr. Jones' uncritical reliance on inputs from Plaintiffs' counsel led to many other data-entry and mathematical errors that underscore the unreliability of her exposure estimates. "[T]he known or potential rate of error" is a key factor when assessing reliability under *Daubert*. 509 U.S. 579, 594 (1993). Here, Dr. Jones' admitted error rate from her original calculation method was **94**%—out of 222 total calculations, 208 of her original estimated lead and arsenic levels were wrong.

Because Dr. Jones assumed that all testing data in the spreadsheets Plaintiffs' counsel provided her were "accurate" and sufficiently "cleaned" (meaning, for example, that duplicate test results had been identified), she did **no** independent work to check the accuracy of those spreadsheets when preparing her opening report. (Ex. 41, Jones Vol. I Tr. 19:3-8, 44:4-45:11.) But after reading the report of defense expert Dr. Scrafford, which identified dozens of data and mathematical errors in her analysis, Dr. Jones realized that any data-cleaning by Plaintiffs' counsel "had not been done to the extent it needed to be done." (*Id.* at 43:9-45:11.) Dr. Jones therefore attempted to correct some of the mistakes identified by Dr. Scrafford and identify additional errors.

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(Id.; see also Ex. 42, Jones Vol. II Tr. 540:12-541:11.) As a result, almost every single one of Dr. Jones' estimated daily lead and arsenic intakes and BLLs changed—and many of them dropped dramatically. (Ex. 23, Jones Rebuttal Report at 15, 22, 29, 34, 40, 46, 54; see also supra at 12.)

Even then, Dr. Jones failed to correct all the errors in her calculations. At deposition, counsel for Defendants showed Dr. Jones additional errors, which prompted Dr. Jones to issue a *third* set of exposure estimates one month after her deposition. See supra at 13. While Dr. Jones now claimsonce again—that her current estimates are "unlikely to change," she provides no basis for her assertion that the glaring flaws in her methodology have been resolved.

These are not the kinds of occasional mistakes that may occur when large datasets are involved. Dr. Jones' opinions were riddled with errors not because of mere inattention to detail, but because she uncritically accepted everything Plaintiffs' counsel told her—much of which was mistaken and inconsistent with existing science or practical reality. That is exactly why experts in the field conduct and control their own analyses, based on their own fact-gathering and scientifically grounded assumptions. Dr. Jones' decision to do otherwise led to manifestly unreliable results.

5. Ms. Barr's "Plausibility" Opinions Are Based on Unsupported **Assumptions that Render Her Opinions Unreliable**

In forming her opinion that the hypothetical menus are "plausible and nutritionally adequate," Ms. Barr likewise accepted numerous unfounded assumptions from Plaintiffs' counseland came up with several of her own—that stand in stark contrast with Ms. Barr's and Dr. Jones' own experience outside the courtroom. These "analytical gap[s]" between real-world data and Ms. Barr's ultimate plausibility opinions render her opinions about the menus—and Dr. Jones' exposure estimates based on those menus—unreliable. Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). Some of the most striking gaps and inconsistencies in Ms. Barr's opinions include:

First, Ms. Barr relied on a series of unscientific assumptions, stacked on top of each other, about the eating patterns of the hypothetical child consuming Plaintiffs' counsel's menus. The hypothetical child imagined by Plaintiffs' counsel (1) consumed only one Defendant's commercial baby foods and no others; and (2) consumed the exact same set of those baby food products (and no others), in the exact same quantities, every single day over the course of a 6-month to 2-year period.

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(See Ex. 20, Hypothetical Menus at 2 ["Assumptions: ... 100% of commercial baby food consumption was Beech-Nut brand."]; see also Ex. 41, Jones Vol. I Tr. 159:25-160:11, 391:1-20; Ex. 42, Jones Vol. II Tr. 428:12-19.)

Ms. Barr did not even attempt to validate those assumptions or determine if they are consistent with actual consumption patterns in U.S. children before concluding the menus were See supra Section III.A. And as both Ms. Barr and Dr. Jones concede, these assumptions do not track real-world experience. Dr. Jones testified that it may not be "normal" for children to "consume only one company's products" (Ex. 41, Jones Vol. I Tr. 157:14-23), and (in the height of understatement) that it "would be a *rare child*" who "eat[s] the exact same baby food products in the exact same servings, day after day for two years" (id. at 158:13-22 [emphasis added]). Indeed, Dr. Jones admitted that she "do[esn't] know" how it would "even be possible to eat the same baby foods in the exact same servings every single day for two years." (Id. at 158:24-159:7.) Ms. Barr likewise testified that "from my experience working with patients, children don't eat the same exact amount of food every day." (Ex. 40, Barr Vol. II Tr. 436:16-437:4 [emphasis added].) But that is the exact assumption on which the lawyer-created menus—and Dr. Jones' exposure estimates—are based. (Ex. 41, Jones Vol. I Tr. 391:1-11 [Q. Would you agree that your exposure calculations for Nurture are based on a hypothetical child eating blueberry and purple carrot Yogis every day from age 7 months to 3 years? A. Yes.].) An expert opinion that contradicts the expert's own experience outside the courtroom is not reliable.

Second, in considering whether the products and quantities identified in the hypothetical menus are "age appropriate" for the selected age ranges, Ms. Barr assumed that because "[n]one of the packaging or marketing materials for the ... products that I reviewed indicated a maximum age or age at which it would be inappropriate to feed the product to a child," those products were necessarily appropriate for consumption at all ages. (Ex. 18, Barr Report at 16 [emphasis added].) As a result, she failed to conduct any scientific (or common sense) assessment of whether a child would plausibly eat the products on the menus throughout the age ranges selected by Plaintiffs' counsel. For example, the hypothetical child consuming Plaintiffs' counsel's Beech-Nut menu is assumed to consume infant rice cereal every day between ages 4 months and 2 years. (Ex. 20,

Hypothetical Menus at 2-4.) Similarly, the hypothetical child consuming Plaintiffs' counsel's Nurture menu is assumed to consume Pea & Spinach Teethers—a product for teething infants—every day between the ages of 6 months and 2 years. (*Id.* at 15.) No child in the real world would consume multiple servings of a "teether" product or infant rice cereal every single day until they are two years old. And the mere absence of an express statement that these products are not intended for those ages was not a scientifically sound basis for Ms. Barr's conclusion that a child plausibly would consume them at those ages.

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Third, despite claiming that whether a product was actually "on the market and ... being sold" was relevant to her plausibility analysis (Ex. 39, Barr Vol. I Tr. 129:13-19), Ms. Barr did not assess whether the products on the hypothetical menus were actually available for sale throughout the 2-year consumption periods chosen by Plaintiffs' counsel. She therefore could not confirm that those products could, in fact, "plausibly" have been consumed throughout those periods. (Id. at 327:16-24, 328:9-329:16, 339:7-20.) And indeed, the hypothetical menus explicitly admit that a number of products were not available throughout Plaintiffs' counsel's chosen consumption windows. (See Ex. 20, Hypothetical Menus at 5, 9, 13, 18, 24, 28, 33.) As just one example, Plaintiffs' counsel chose 2016-2018 as the consumption period for the hypothetical Nurture menu. But the two Nurture "bowls" included on the menu—which the hypothetical child is assumed to consume every day for an entire year—only came onto the market sometime in 2018, making it factually impossible for any child to have consumed those bowls every day as contemplated by the menus. (Id. at 18.) Despite giving no consideration to this inconsistency—and others like it—in her plausibility analysis, Ms. Barr asserted that a child could still have plausibly consumed all of these products throughout Plaintiffs' counsel's chosen time periods depending on "expiration dates" and "shelf life." (Ex. 39, Barr Vol. I 330:16-331:25.) A plausibility opinion "that is connected to existing data only by the *ipse dixit* of the expert" is not admissible under Rule 702. Engilis v. Monsanto Co., -- F.4th -- , 2025 WL 2315898, at *5 (9th Cir. Aug. 12, 2025) (quoting Joiner, 522 U.S. at 146).

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B. Ms. Barr's and Dr. Jones' Opinions Are Inadmissible Because the Hypothetical Menus and Consumption Patterns Plaintiffs' Counsel Directed Them to Assume Do Not Reflect "Realistic" Exposure Levels

Putting aside the methodological flaws in these opinions, Dr. Jones' exposure estimates do not "fit" the general causation question at hand because they do not reflect "realistic" levels of exposure to lead or arsenic from consuming Defendants' baby food products. Plaintiffs can establish general causation only if their experts provide reliable opinions that the consumption of lead and arsenic in Defendants' baby food products can cause autism and/or ADHD at exposure levels U.S. children "realistically" may experience. Hardeman v. Monsanto Co., 997 F.3d 941, 963 (9th Cir. 2021). Neither Ms. Barr's nor Dr. Jones' opinions provide reliable evidence of a "realistic" level of lead or arsenic exposure from Defendants' products because the consumption patterns created by Plaintiffs' counsel are anything but realistic.

Ms. Barr and Dr. Jones do not even suggest that the hypothetical menus reflect typical consumption patterns for U.S. children. To the contrary, Ms. Barr and Dr. Jones repeatedly disclaimed any suggestion that the menus are "typical" or "average" in any way. (Ex. 40, Barr Vol. II Tr. 495:3-7 ["[M]y charge wasn't to see if it was a typical child or the average ... child."]; Ex. 41, Jones Vol. I Tr. 157:4-12 [agreeing that she "did not do an exposure assessment for a typical child in the US population"].) Dr. Jones went so far as to admit that in forming her opinions, she did not even consider whether "any of the hypothetical menus ... are similar to menus consumed by *any child in the United States*." (Ex. X, Jones Vol. I Tr. 74:1-8.)

Ms. Barr and Dr. Jones also do not claim that these consumption patterns (or Dr. Jones' exposure estimates) correspond in any way to the actual, real-world exposures of the plaintiffs in this MDL. Dr. Jones admitted that she does not know if any of the hypothetical menus "are similar to the menu of products consumed by any child in this litigation." (*Id.* at 73:13-23.) Ms. Barr, too, has no knowledge of "any specific child and their intake patterns" and did nothing to determine if the hypothetical menus "are actually representative of any specific child who has filed a lawsuit in this litigation." (Ex. 39, Barr Vol. I Tr. 333:12-19, 334:4-12.)

Ms. Barr nonetheless offers the opinion that the hypothetical consumption patterns are "plausible" because it is "possible" that "a child" could consume them—in her words, "I mean even one child can make something plausible." (Id. at 275:6-7.) Setting aside the factual impossibility of, for example, a child consuming the exact same baby food products in the exact same quantities every single day for over two years, that is not the relevant standard. Hardeman requires proof of an exposure level that real people, in the real world, on a population basis, "realistically may have experienced." 997 F.3d at 963. A theoretical "possibility" that a child could consume baby foods in a pattern never before seen by either of these Plaintiffs' experts (or anyone else) cannot make it "realistic."

Plaintiffs proffer no evidence, beyond Ms. Barr's *ipse dixit* assertions about "possibilities," that the hypothetical menus would realistically be consumed by any U.S. child. Ms. Barr's say-so is plainly not enough to reliably reach this conclusion. *See Engilis*, -- F.4th -- , 2025 WL 2315898, at *5; *Joiner*, 522 U.S. at 146. Nor is Ms. Barr's opinion on what might be "possible" a scientifically sound basis on which to rest Dr. Jones' reliance on those menus to calculate estimated exposure levels that are supposed to reflect exposures that U.S. children "realistically" may experience, *Hardeman*, 997 F.3d at 963—or for Plaintiffs' causation experts' reliance on those (flawed) exposure estimates to support their causation opinions.

Under Rule 702, expert testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue." *Engilis*, -- F. 4th -- , 2025 WL 2315898, at *4 (citation omitted). If an expert's opinions do not "fit" the pertinent inquiry, they should not be admitted. Because Dr. Jones' exposure estimates based on the hypothetical menus do not reflect a "realistic" level of exposure to lead or arsenic from the products at issue, they are neither reliable nor relevant to the general-causation question and should be excluded.

IV. CONCLUSION

For the foregoing reasons, the Court should exclude Ms. Barr's and Dr. Jones' opinions in their entirety.

Dat	ted: September 26, 2025	WILLIAMS & CONNOLLY LLP			
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Da	ted: September 26, 2025	KING & SPALDING LLP			
		By: /s/ Livia M. Kiser			
		Livia M. Kiser			
		Michael Anthony Lombardo			
		Todd P. Davis (pro hac vice)			
		Attorneys for Defendants Beech-Nut Nutrition Company and Walmart Inc.			
		- '			
Date	ed: September 26, 2025	DLA PIPER LLP (US)			
		By: <u>/s/ <i>Brooke Killian Kim</i></u> Brooke Killian Kim			
		Mary Gately (pro hac vice)			
		Loren H. Brown (pro hac vice)			
		Attorneys for Defendant Nurture, LLC			
Da	ted: September 26, 2025	COVINGTON & BURLING LLP			
		D //MC1 1871 .			
		By: /s/ <i>Michael X. Imbroscio</i> Michael X. Imbroscio (<i>pro hac vice</i>)			
		Phyllis A. Jones (pro hac vice)			
		David N. Sneed (pro hac vice)			
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1	Dated: September 26, 2025	GORDON REES SCULLY MANSUK		LY MANSUKHANI, LLP	
2	,	By: /s/ Michael R. Klatt			
3		Michael R. Klatt (pro hac vice) Nancy Mae Erfle (pro hac vice) Attorneys for Defendant Sprout Foods, Inc. DECHERT LLP			
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5	Dated: September 26, 2025				
6	Dated. September 20, 2023				
7		By: <u>/s/ Hope Freiwald</u> Hope S. Freiwald (<i>pro hac vice</i>)			
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CERTIFICATE OF SERVICE

I certify that on September 26, 2025, I electronically filed the foregoing DEFENDANTS' BRIEF ISO JOINT MOTION TO EXCLUDE PLAINTIFFS' EXPOSURE EXPERTS RACHAEL JONES AND PRISCILLA BARR using the ECF system, which sent notification of such filing to all counsel of record.

> /s/ Neelum J. Wadhwani Neelum J. Wadhwani